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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/613,749      | 07/03/2003  | Arthur M. Krieg      | C01037.70041.US     | 6452             |

23628 7590 01/23/2006

WOLF GREENFIELD & SACKS, PC  
FEDERAL RESERVE PLAZA  
600 ATLANTIC AVENUE  
BOSTON, MA 02210-2211

EXAMINER

MINNIFIELD, NITA M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/613,749 | <b>Applicant(s)</b><br>KRIEG, ARTHUR M. |  |
|                              | <b>Examiner</b><br>N. M. Minnifield  | <b>Art Unit</b><br>1645                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-12, 14, 19-21, 23, 28-33, 44 and 100-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) <u>2pgs</u>                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 1-5,8-15,19-21,23,28-33,44,46-58,64-66,71-74,77-81,84,85,89,90,95,96,98 and 100-102.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5,13,15,46-58,64-66,71-74,77-81,84,85,89,90,95,96 and 98.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 5,13,15,46-58,64-66,71-74,77-81,84,85,89,90,95,96 and 98.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment filed October 13, 2005 is acknowledged and has been entered. Claims 6, 7, 16-18, 22, 24-27, 34-43, 45, 59-63, 67-70, 75, 76, 82, 83, 86-88, 91-94, 97 and 99 have been canceled. Claims 1, 2, 19 and 20 have been amended. New claims 100-102 have been added. Claims 1-5, 8-15, 19-21, 23, 28-33, 44, 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 90, 95, 96, 98 and 100-102 are now pending in the present application. All rejections have been withdrawn in view of Applicant's amendments to the claims and/or comments set forth in the amendment with the exception of those discussed below.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 5, 13, 15, 46-58, 64-66, 71-74, 77-81, 84, 85, 89, 90, 95, 96 and 98 have withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 27, 2004.
4. Claims 1, 3, 8-10, 17, 18, 20, 21, 23 and 30-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 41-46, 52-56 and 58 of copending Application No. 10/816220 (2004/0076905). Although the conflicting claims are not identical, they

are not patentably distinct from each other because both applications claim compositions comprising an immunostimulatory nucleic acid molecule, an antigen and optionally an adjuvant. Application 10/613749 claims SEQ ID NO: 1 and Application 10/816220 claims SEQ ID NO: 148; these sequences are the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This provisional rejection is maintained for the reasons of record. It is noted that the October 13, 2005 amendment set forth the following statement for the record. "Without conceding the Examiner's position, Applicant defers substantive rebuttal until the cited are allowable." (see p. 12 of the amendment).

5. Claim 102 is rejected under 35 U.S.C. 102(a) as being anticipated by Olek et al (WO 2002/18632 or WO 2001/92565).

Claim 102 is directed to a composition comprising an immunostimulatory nucleic acid comprising the nucleotide sequence of SEQ ID NO: 1, wherein the immunostimulatory nucleic acid is single stranded.

Olek et al, WO 2002/18632, discloses a composition comprising the nucleotide sequences (claims; abstract). SEQ ID NO: 4789, 4790, 19850, 19849 and 5396 comprise Applicant's claimed SEQ ID NO: 1 (please see the attached sequence search result print out). The prior art sequences have at least four CpG motifs.

Olek et al, WO 2001/92565, discloses a composition comprising the nucleotide sequences (claims; abstract). SEQ ID NO: 244 comprises Applicant's

claimed SEQ ID NO: 1 (please see the attached sequence search result print out).  
The prior art sequence has at least four CpG motifs.

Since the Patent Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

6. Claims 1-4, 8-12, 14, 19-21, 23, 29-33, 44 and 100-102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in that it is not clear what is encompassed in the claimed invention. The claim recites open claim language ("comprising"), which could be a vector or plasmid. The claim only recites immunostimulatory nucleic acid. Further, claims 3, 4, 8 and 101 recite an antigen. Is this a peptide antigen or does the immunostimulatory nucleic acid encode the claimed antigen? It is not clear what Applicant intends.

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

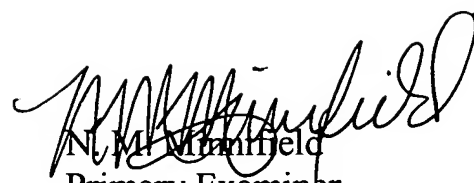
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Art Unit: 1645

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N. M. Minfield  
Primary Examiner  
Art Unit 1645

NMM

January 12, 2006